

REMARKS

Claims 1-29 were pending in this application. Claims 3 and 8-28 have been cancelled without prejudice or disclaimer. Claim 29 has been amended. Claims 30-51 have been added. Therefore, Applicants respectfully submit that claims 1, 2, 4-7 and 29-51 are in the case. No new matter has been added. Support for new claims 30-51 can be found in claim 3 as originally pending.

Applicants respectfully acknowledge the Examiner's allowance of the elected species, 9-t-butyl-6-deoxy-5-acetylcarbonyloxytetracycline.

The Examiner withdrew claims 2 and 4-6 because she believed that Applicants' elected species, 9-t-butyl-6-deoxy-5-acetylcarbonyloxy tetracycline, was not encompassed by the definition of compounds of formula I. In particular, the Examiner stated that "the definition of R₂ as defined by claim 2 does not include an acyloxy or an acylcarbonyloxy group as recited by claim 6 and the elected species."

Applicants traverse the withdrawal of the claims from examination. The definition of R₂ as defined by claim 2, does include the acylcarbonyloxy substituent of Applicants' elected invention. The elected species is encompassed by formula I of claim 2, because acylcarbonyloxy substituents are included in the definition of "alkoxy" in the specification at page 9, line 34, through page 10, line 17. For example, at page 10, line 15, the term "alkoxy" is defined as "O-alkyl." The term "alkyl" is defined at page 9, line 34 through page 10, line 14, as including "substituted alkyls." Examples of substituents include alkyl carbonyl groups (see page 10, line 4).

Therefore, Applicants respectfully submit that since claims 2 and 4-6 read on the elected species, these claims are properly presented for examination and respectfully request that the Examiner examine these claims.

Rejection of Claims 1, 3, and 29 under 35 U.S.C. § 102(b)

Claims 1, 3 and 29 were rejected under 35 U.S.C. § 102(b) as anticipated by Bernardi *et al.* ('942). According to the Examiner, the '942 patent teaches a generic group of 5,9-substituted tetracycline derivatives including 9-t-butyl-6-deoxy-5-hydroxytetracycline. Applicants traverse.

Applicants' claimed invention is directed to 5,9-substituted tetracycline compounds. Applicants' specification defines "5,9-substituted tetracycline compounds" at page 3, lines 28-31 as being "substituted by other than hydroxy or hydrogen at the 5- and 9- ring positions."

Accordingly, Applicants respectfully submit that the compounds disclosed in the '942 patent are not 5,9-substituted tetracycline compounds as claimed, because the compounds disclosed in '942 have a hydroxyl group at the 5- position of the tetracycline ring. The '942 reference therefore does not anticipate the claimed invention, i.e., compounds having substituents other than hydroxy or hydrogen at the 5 position of the tetracycline ring system. Therefore, Applicants respectfully request that the rejection of claims 1, 3 and 29 under 35 U.S.C. § 102(b) be withdrawn.

Rejection of Claims 1 and 29 under 35 U.S.C. § 102(b)

Claims 1 and 29 were rejected under 35 U.S.C. § 102(b) as anticipated by Bernardi *et al.* ('384). The '384 patent was said to disclose a group of tetracycline derivatives which include 9-methylthiomethyl- α -6-deoxy-5-hydroxy-tetracycline and 9-methyl- α -6-deoxy-5-hydroxytetracycline. Applicants traverse.

As noted above, Applicants' claims are directed to 5, 9-substituted compounds and pharmaceutical compositions, i.e., those substituted by other than hydroxy or hydrogen at the 5- and 9- ring positions. As such, Applicants respectfully submit that the '384 patent does not anticipate the presently claimed invention. Therefore, Applicants respectfully request that the Examiner withdraw the rejection of claims 1 and 29 under 35 U.S.C. § 102(b).

Rejection of Claims 1, 3, 7 and 29 under 35 U.S.C. § 103(a)

Claims 1, 3, 7 and 29 were rejected under 35 U.S.C. § 103(a) as unpatentable over Bernardi *et al.* ('942). The Examiner argued that the '942 patent "teaches a generic group of 5,9- substituted tetracycline derivatives" including 9-t-butyl- α -6-deoxy-5-hydroxytetracycline, and that the present claims differ from the present claims by "reciting additional tetracycline derivatives not taught or exemplified by the reference", and concluded that it would have been obvious to one of ordinary skill in the art to select any species of the genus because of a "reasonable" expectation that any of the species would have similar properties. Applicants traverse.

As noted above by Applicants, the '942 patent does not teach or suggest, 5,9-substituted tetracycline compounds as presently claimed. The '942 patent discloses only compounds having, at most, a hydroxyl group at the 5- position of the tetracycline ring. One of ordinary skill in the art having the '942 patent at their disposal would not find any teaching or suggestion for replacement of a hydroxyl group at position 5 with, e.g.,

alkanoyl; aroyl; alkaroyl; carbocyclic aryl, heteroaromatic, alkyl; alkenyl; alkynyl; alkoxy; alkylthio; alkylsulfinyl; alkylsulfonyl; alkylamino; or an aryalkyl group, as presently claimed. Furthermore, Applicants direct the Examiner's attention to the unexpected benefits of the claimed 5,9-substituted compounds; for example, at page 39 of the present specification, certain 5, 9- substituted tetracycline compounds are demonstrated to have unexpectedly high antibiotic activity.

Therefore, since the presently claimed invention is not obvious over the '942 patent, Applicants respectfully submit that withdrawal of the rejection of claims 1, 3, 7, and 29 under 35 U.S.C. § 103(a) is in order, and is respectfully requested.

Rejection of Claims 1, 3, 7, and 29 under 35 U.S.C. § 103(a)

Claims 1, 3, 7, and 29 were rejected under 35 U.S.C. § 103(a) as being unpatentable over Bernardi *et al.* ('384). The Examiner argued that the '942 patent "teaches a generic group of 5,9- substituted tetracycline derivatives" including 9-methylthiomethyl-alpha-6-deoxy-5-hydroxytetracycline and 9-methyl-alpha-6-deoxy-5-hydroxytetracycline, and that the present claims differ from the present claims by "reciting additional tetracycline derivatives not taught or exemplified by the reference", and concluded that it would have been obvious to one of ordinary skill in the art to select any species of the genus because of a "reasonable" expectation that any of the species would have similar properties. Applicants traverse.

As noted above by Applicants, the '942 patent does not teach or fairly suggest 5,9-substituted tetracycline compounds as presently claimed. The '942 patent discloses only compounds having, at most, a hydroxyl group at the 5- position of the tetracycline ring. One of ordinary skill in the art, having the '942 patent at their disposal, would not find a teaching or suggestion for the replacement of a hydroxyl group at position 5 with, e.g., alkanoyl; aroyl; alkaroyl; carbocyclic aryl, heteroaromatic, alkyl; alkenyl; alkynyl; alkoxy; alkylthio; alkylsulfinyl; alkylsulfonyl; alkylamino; or an aryalkyl group, as presently claimed. Furthermore, the present specification describes unexpected benefits of the claimed 5,9-substituted compounds; for example, as seen at page 39 of the present specification.

Therefore, since the presently claimed invention is not obvious over the '384 patent, Applicants respectfully submit that withdrawal of the rejection of claims 1, 3, 7, and 29 under 35 U.S.C. § 103(a) is in order, and is respectfully requested.

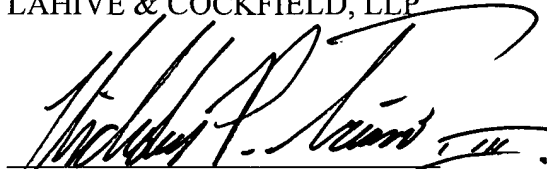
SUMMARY

Cancellation of and/or amendments to the claims should in no way be construed as an acquiescence to any of the Examiner's objections and/or rejections. The cancellation of the claims is being made solely to expedite prosecution of the above-identified application. Applicants reserve the option to further prosecute the same or similar claims in the present or another patent application.

It is respectfully submitted that claims 1, 2, 4-7 and 29-51 are in condition for allowance and a Notice of Allowability is in order and is respectfully requested. If a telephone conversation with Applicants' attorney would expedite the prosecution of the above-identified application, the Examiner is encouraged to call Applicants' attorney at (617) 227-7400.

Respectfully submitted,

LAHIVE & COCKFIELD, LLP



Nicholas P. Triano, III, Esq.
Registration No. 36,397
Attorney for Applicant(s)

LAHIVE & COCKFIELD, LLP
28 State Street
Boston, MA 02109-1784
(617) 227-7400
Fax: (617) 742-4214

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